2011 PA Super 23

MARY DANIEL and THOMAS DANIEL, SR.,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellants	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH LABORATORIES, INC., WYETH PHARMACEUTICALS, DIV. OF WYETH, DIV. OF AMERICAN HOME PRODUCTS CORP., WYETH, INC. A/K/A AMERICAN HOME PRODUCTS CORP.,	:	
	:	
Appellees	:	No. 2626 EDA 2007

Appeal from the Order entered August 24, 2007,
Court of Common Pleas, Philadelphia County,
Civil Division at No. June Term, 2004, No. 002368

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Appellees	:	
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WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH LABORATORIES, INC., and WYETH PHARMACEUTICALS, DIVISION OF WYETH,	:	
	:	
Appellants	:	No. 2690 EDA 2007

*Former Justice specially assigned to the Superior Court.

Appeal from the Order entered August 24, 2007,
Court of Common Pleas, Philadelphia County,
Civil Division at No. June Term, 2004, No. 002368

BEFORE: DONOHUE, ALLEN and FITZGERALD*, JJ.
*****Petition for Reargument Filed February 22, 2011*****
OPINION BY DONOHUE, J.: Filed: February 7, 2011
*****Petition for Reargument Denied April 14, 2011*****

Appellants, Mary Daniel ("Daniel") and Thomas Daniel, Sr. ("Daniel, Sr.," collectively, the "Daniels"), appeal from the trial court's orders granting motions for a new trial on liability issues and for judgment notwithstanding the verdict ("JNOV") on punitive damages. Appellee, Wyeth Pharmaceuticals, Inc., *et al.* ("Wyeth"), cross-appeals four rulings of the trial court. For the reasons set forth herein, we reverse the trial court's order granting Wyeth's post-trial motion for a new trial and reinstate the jury's verdict on compensatory damages. We likewise reverse the trial court's grant of JNOV on punitive damages and reinstate the jury's verdict awarding punitive damages. Wyeth's cross-appeal is denied.

This case arises from Daniel's use of a drug manufactured by Wyeth known as Prempro. Prempro is a combination of two drugs: estrogen and progestin. Physicians regularly prescribed estrogen (sold by Wyeth as "Premarin"[1]) as a hormone replacement drug until 1975, when studies

[1] Wyeth began selling Premarin in 1942. Another company (Upjohn) began selling a synthetic progestin (known as Provera) in or around 1959. Prior to the 1960s, the Food & Drug Administration ("FDA") lacked the power to approve drugs for sale, and when it obtained such authority existing drugs

revealed that the use of estrogen was causing endometrial and other below-the-waist cancers. In response, physicians began to prescribe a combination of Premarin and progestin (for endometrial protection).

In 1983, Wyeth sought FDA approval for the sale of a single pill containing both estrogen and progestin. In its initial application, Wyeth did not propose to do any new studies, instead relying on then-available studies regarding the efficiency and safety of the two drugs in combination. The FDA denied the application, advising Wyeth that existing studies were inadequate. In 1991 the FDA approved Wyeth's proposal to conduct clinical trials of the combination drug (known as the "Prem-Pack Protocols"). After these clinical trials were completed, the FDA approved the sale of the one pill combination drug named Prempro. In so doing, the FDA required Wyeth to make various disclosures on its product information and package inserts, including the following warning on Prempro's information sheet:

> *Breast cancer.* Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy.
>
> The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased

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already on the market were grandfathered. As such, neither Premarin nor Provera – when sold separately- had to undergo any FDA approval process.

> risk in those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship. In a one year clinical trial of PREMPRO, PREMPHASE™, and Premarin alone, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments, while no new cases were detected among 347 women who received Premarin alone. The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population … Women on hormone replacement therapy should have regular breast examinations and should be instructed in breast self-examination, and women over the age of 50 should have regular mammograms.

Physicians' Desk Reference 1999, Notes of Testimony ("N.T."), 1/17/07 (Afternoon Session ("AS")), at 26-29; Wyeth's Motion for Summary Judgment Based on the Learned Intermediary Doctrine, Exhibit C.[2] The FDA did not require, and Wyeth did not include, a prominent "black box" warning of any risks of contracting breast cancer associated with Prempro.[3]

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[2] As the Concurring Opinion notes, the certified record in this case is incomplete in certain respects, particularly with respect to the lack of trial exhibits. We cannot agree, however, that this impeded effective appellate review in this case. We note, for example, that each of the citations to evidence set forth hereinbelow is to evidence contained in the certified record.

[3] During the time Daniel took Prempro, the patient package insert (which was included with each month's supply of pills) included a section entitled "Risks of Estrogens and/or Progestins" that included a discussion of breast cancer. This discussion noted that while "most studies have not shown a higher risk of breast cancer in women who have ever used estrogens," "some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for long periods of time (especially more than 10 years"), or who used high doses for shorter periods of time." N.T., 1/17/07 (MS), at 82; Wyeth's Motion for Summary Judgment Based on the Statute of Limitations, Exhibit B. The package insert further

A comprehensive study of the use of estrogen and progestin in post-menopausal women by the National Institutes of Health ("NIH") was already underway when the FDA approved Prempro in 1994. Beginning in 1991, one of the areas of inquiry of the Women's Health Initiative ("WHI") study was the risk of breast cancer from taking estrogen and progestin together. The NIH published the results in July 2002, which included a finding that there was a significant causal link between the combined use of estrogen and progestin and breast cancer. In fact, the NIH noted its study had to be terminated three years prior to its scheduled completion because of an unacceptably high incidence of invasive breast cancer among the participants in its study. In response, Wyeth changed the language on its product information and package inserts for Prempro to include a "black box" warning identifying invasive breast cancer as a risk associated with taking Prempro.

On June 30, 2004, the Daniels, residents of the state of Arkansas, filed a complaint in the Court of Common Pleas of Philadelphia County, alleging that in 1999 Daniel's doctor, John Haggard, M.D., prescribed for her a hormone therapy drug, Prempro, manufactured by Wyeth. Complaint, ¶ 2-3. Daniel further alleged that she continued to ingest Prempro until August

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warned that "[t]he effects of added progestin on the risk of breast cancer are unknown. Some studied have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. Others have not." ***Id.***

9, 2001, at which time she was diagnosed with breast cancer (moderately differentiated invasive ductal carcinoma, extending to one margin) and had to undergo surgery and chemotherapy as a result. ***Id.*** at ¶ 4. Daniel asserted claims against Wyeth for negligence, breach of express warranty, and fraud, and Daniel, Sr. asserted a claim for loss of consortium. ***Id.*** at ¶ 7.

After a four week trial, on January 29, 2007 the jury awarded the Daniels $1,681,650 in compensatory damages ($1,000,000 to Daniel, $500,000 to Daniel, Sr., and $181,650 in delay damages). The trial court summarized the jury's findings as follows:

> The jury concluded that Wyeth negligently failed to provide proper warnings regarding the risks of breast cancer to [Daniel's] prescribing physician during the time that she took Prempro. The jury further concluded that Wyeth's negligence was a cause of her physician's decision to prescribe Prempro to her, and that Prempro was a factual cause of her injury, specifically breast cancer or its growth. Additionally, the jury found that Wyeth's conduct was sufficient to award punitive damages to [the Daniels].

Trial Court Opinion, 4/23/07, at 1-2.

On January 30, 2007, Wyeth filed a motion for JNOV on the availability of punitive damages which, after hearing oral argument, the trial court granted. When the Daniels indicated that they intended to appeal this ruling, the trial court conducted a brief jury trial with the same jury so that this Court would not have to remand the case for re-trial in the event of a

reversal. The parties presented additional evidence, including information regarding Wyeth's net worth, and the jury returned an award of punitive damages (which the trial court then formally struck, in accordance with its JNOV ruling). At Wyeth's request, and in order not to prejudice the jury in another case being tried at the same time in another courtroom, the trial court sealed the amount of punitive damages awarded.

On February 1, 2007, Wyeth filed a motion for post-trial relief on causation issues. On February 8, 2007, Wyeth filed a second motion for post-trial relief on other liability issues. By orders dated April 23, 2007, the trial court denied both of these motions and issued a written opinion in support of the grant of Wyeth's motion for JNOV on punitive damages. On June 14, 2007, the Daniels filed a notice of appeal from the trial court's grant of JNOV on punitive damages, and on June 15, 2007 Wyeth filed two notices of cross-appeal from the trial court's April 23, 2007 orders denying its motions for post-trial relief.

On May 14, 2007, Wyeth filed a supplemental motion for post-trial relief seeking a new trial based upon after-discovered evidence. Specifically, Wyeth claimed that Dr. Lester Layfield, one of the expert witnesses whose testimony the Daniels offered at trial (through the reading a portion of his deposition), had given a deposition in another case[4] in April 2007 in which

[4] ***Zandi v. Wyeth***, No. 27CV06-6744, Hennepin County, Minnesota District Court, Fourth Judicial District (hereinafter, the "***Zandi***" case).

he had recanted his testimony in the case *sub judice*. The trial court,[5] after considering Wyeth's supplemental motion, the Daniels' response thereto, and an affidavit from Dr. Layfield, ruled that Dr. Layfield had in fact recanted his testimony and that, if his recanted testimony had been presented to the jury in this case, the jury would likely have reached a different result. Trial Court Opinion, 8/24/08, at 14-18. Concluding that Dr. Layfield's affidavit denying recantation lacked credibility, by order dated August 14, 2007 the trial court granted Wyeth's supplemental motion and ordered a new trial.

On September 18, 2007, the Daniels filed a second notice of appeal, this one including both the trial court's grant of JNOV on punitive damages and the grant of Wyeth's motion for a new trial. Wyeth promptly filed another notice of cross-appeal. This Court thereafter dismissed both the Daniels' initial notice of appeal and Wyeth's initial cross-appeals as moot, leaving as pending the Daniels' second appeal and Wyeth's second cross-appeal. This Court initially issued an order *sua sponte* dismissing Wyeth's second cross-appeal, but by order dated October 26, 2009 this Court reinstated said cross-appeal.

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[5] The Honorable Judge Myrna Field served as the judge at trial. Sadly, Judge Field died shortly after her issuance of the two orders and written opinion on April 23, 2007. The case was then assigned to the Honorable Judge Allen Tereshko, who ruled on Wyeth's supplemental motion for post-trial relief.

The Daniels present the following issues for our consideration in this appeal:

> 1. Whether the trial court erred in granting judgment notwithstanding the verdict on [the Daniels'] claims for punitive damages after a four-week trial based on its conclusion that allegations that a drug company "failed to test" a defective product cannot merit punitive damages, notwithstanding [the Daniels'] substantial evidence showing [Wyeth's] awareness for over two decades of the risk that women taking its hormone therapy drugs would develop breast cancer, its consistent refusal to conduct any study or evaluation of this risk, and its deliberate efforts to discredit scientific data confirming the risk.
>
> 2. Whether the trial court committed reversible legal error in granting a new trial based on "newly discovered evidence" of a witness allegedly recanting his testimony in a subsequent case when (i) the subsequent testimony was not new or different from what the witness originally testified; (ii) the witness explicitly reaffirmed the only part of his prior opinion that could have been relied upon at trial; and (iii) the causation opinion at issue was cumulative and corroborative of at least eight separate and independent pieces of evidence supporting causation.

Appellants' Brief at 3.

In its cross-appeal, Wyeth raises the following four issues for our review:

> 1. In this prescription drug case based on alleged failure to warn, is Wyeth entitled to a new trial where evidence of subsequent remedial measures (in the form of warnings that post-dated Daniel's use of the drug) was admitted to prove negligence.
>
> 2. In this prescription drug case based on alleged failure to warn, is Wyeth entitled to judgment in its

favor where the physician who prescribed the drug for Daniel was never asked whether an adequate warning would have changed his decision to prescribe the drug -- and there was no other evidence of proximate causation.

3. In this prescription drug case based on alleged failure to warn, is Wyeth entitled to judgment in its favor where Daniel failed to present expert testimony by a *physician* that the breast cancer warnings which Wyeth provided to physicians were inadequate.

4. In this prescription drug case, is Wyeth entitled to judgment in its favor where there was no reliable scientific evidence that use of the drug for less than two years causes breast cancer.

Appellee's Brief at 2-3.[6]

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[6] In its initial brief, Wyeth set forth two additional issues, both asserting that the Daniels' claims were preempted by federal law. ***Id.*** at 3. In its cross-appeal reply brief, however, Wyeth indicated that it no longer intended to pursue these claims. Appellee's Cross-Appeal Reply Brief at 1 n.1. ***See Wyeth v. Levine***, 129 S.Ct. 1187, 1191 (2009) (FDA approval of prescription drug's warning label does not preempt state law failure to warn claim).

Also, in its Pa.R.A.P. 1925(b) statement, Wyeth raised two issues relating to the provisional second stage of the trial during which the jury determined the amount of the punitive damage award: (1) whether the trial court had subject matter jurisdiction to hold the proceeding after granting the motion for JNOV, (2) whether the amount of punitive damages awarded by the jury could be reinstated if this Court were to reverse the trial court's grant of JNOV, since the trial court denied certain of Wyeth's proposed jury instructions regarding the proper method of computation of a punitive damage award (including instructions regarding the relationship between punitive and compensatory damages, the bar to punishment for out-of-state conduct, the bar to punishment for unlawful conduct, and the relevance of Wyeth's financial condition). ***See*** Wyeth's Statement of Matters Complained of on Appeal at 3-4 (issues 8 and 9). With respect to this second issue, Wyeth stated that "[t]he Court's refusal to give these instructions left the jury with an incomplete, misleading, and unfairly prejudicial account of the

With respect to the Daniels first issue on appeal, our standard of review regarding the trial court's grant of a new trial on the basis of after-discovered evidence is whether the trial court abused its discretion or committed an error of law that controlled the outcome of the case. ***Commonwealth ex rel. Meyers v. Stern***, 509 Pa. 260, 264-65, 501 A.2d 1380, 1382 (1985). In conducting this review, there is a presumption that the trial court was justified in granting the new trial. ***Bellettiere v. City of Philadelphia***, 367 Pa. 638, 642, 81 A.2d 857, 859 (1951).

The legal requirements for the grant of a new trial based upon after-discovered evidence are well established: the evidence must have been discovered after the trial and must be such that it could not have been obtained at the trial by reasonable diligence, must not be cumulative or merely impeach credibility, and must be such as would likely compel a different result. ***Stern***, 509 Pa. at 264-65, 501 A.2d at 1382; ***Hornick v. Bethlehem Mines Corp.***, 310 Pa. 225, 228, 165 A. 36, 37 (1933). Our Supreme Court has expanded the basis for granting a new trial to include

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law of punitive damages. Therefore, a new trial on the amount of punitive damages as well as the other issues would still be required." ***Id.*** (issue 9).

Wyeth did not include either of these issues in the "Statement of Questions Involved" section of its appellate brief, however, and did not thereafter mention them in the "Argument" section of the brief. Accordingly, these issues are waived for purposes of appeal. ***See, e.g.***, ***Mooney v. Greater New Castle Development Corp.***, 510 Pa. 516, 524 n.4, 510 A.2d 344, 348 n.4, *cert denied*, 479 U.S. 915 (1986); ***Dickens v. Barnhart***, 711 A.2d 513, 515 n.5 (Pa. Super.), *appeal denied*, 556 Pa. 709, 729 A.2d 1129 (1998).

cases involving recanted testimony. ***Township of Perkiomen v. Mest***, 513 Pa. 598, 603, 522 A.2d 516, 519 (1987); ***Blake v. Marinelli***, 357 Pa. 314, 317, 53 A.2d 550, 552 (1947).

In this case, the trial court found that Dr. Layfield had recanted his opinion regarding the cause of Daniel's cancer by the time of trial, and that Daniel nevertheless presented his testimony (by way of the reading of his deposition) without informing anyone of the recantation. Trial Court Opinion, 9/24/08, at 9-11. Specifically, based upon a small portion of Dr. Layfield's deposition testimony, the trial court found that he "testified that the use of Prempro caused any cancerous lesions that may not have advanced to cancerous lesions, to proliferate to cancer." ***Id.*** at 9. At his subsequent deposition in the ***Zandi*** case four months later, however, the trial court decided that Dr. Layfield "testified that he no longer held that opinion and would not be able to testify linking Daniel's cancer with the use of Prempro as he had done at his earlier deposition in the Daniel's case because of the short term duration of time in which she took Prempro." ***Id.*** As a result, the trial court ruled that Dr. Layfield had recanted the opinion he provided in his Daniels' deposition (and which was later read to the jury), that this recantation could not have been discovered by Wyeth upon reasonable diligence, that it was not cumulative or for purposes of impeachment, and would likely to have compelled a different result in the Daniels' trial. ***Id.*** at 11.

Based upon our review of the record on appeal, the trial court's finding that Dr. Layfield recanted his testimony in the ***Zandi*** deposition was based upon an incomplete consideration of Dr. Layfield's testimony in this case. Dr. Layfield testified that he is an anatomic pathologist and was initially hired in connection with the Daniels' litigation for two purposes: (1) to perform a "Ki-67"[7] analysis on certain specimens, and (2) to determine whether he had any opinions regarding the relationship between hormone replacement therapy and Daniel's breast cancer. N.T., 1/17/07 (AS), at 84, 87-88. With regard to the second of these two inquiries, Dr. Layfield testified that in his opinion hormone replacement therapy, in some women, "is a promoter of the oncogenic process by driving proliferation," and that while there are "many causes of breast cancer," "you need something that causes proliferation [and] also need something that induces mutations." ***Id.*** at 92-93. Specifically with respect to Daniel, Dr. Layfield then offered the following testimony:

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[7] A Ki-67 test measures the proliferation or growth of a tumor. N.T., 1/12/07 (MS), at 74. After a biopsy confirmed their diagnosis of a tumor of the breast, Daniel's doctors instructed her to stop taking Prempro. ***Id.*** at 86. After surgery to remove the tumor a week later, tissue samples were compared to see if the growth rate of the tumor had increased since cessation of taking Prempro. ***Id.*** The Ki-67 test performed by Dr. Layfield showed that during the week between the biopsy and the surgery, during which she was no longer ingesting Prempro, the rate of growth of Daniel's tumor had slowed from 29 percent to just 7.6 percent. ***Id.*** Wyeth's experts did not contest that a Ki-67 test is "a legitimate test to look at a specific area of a tumor and look at how many cells appear to be growing in that area." N.T., 1/22/07, at 122.

> Q. Now, do you have a knowledge as we sit here to date of what it was that you believe the hormone therapy caused to proliferate?
>
> A. The hormone therapy, to my personal, professional opinion, could have and would have – would have caused proliferation of all the epithelial lesions at the time the hormonal therapy was initiated and sustained. In other words …
>
> Q. All right, whatever the woman – whatever the lady already had, it would cause proliferation; is that what you're saying?
>
> A. Right. Which in my professional opinion was a premalignant lesion that was not obligated to progress to cancer, but when induced to proliferate by the hormone replacement therapy, did indeed proliferate, which allowed it to undergo not only additional mutations because it's proliferating cells that are most at risk for having mutations occur, but it always was important for having the premalignant lesions increase in size.

Id. at 94.

The trial court relied exclusively on this testimony in deciding that Dr. Layfield subsequently recanted in the ***Zandi*** deposition. This testimony, *taken alone*, does appear to indicate that Dr. Layfield was of the opinion that Daniel's ingestion of Prempro caused a premalignant lesion to proliferate and, after mutations, become cancerous. Dr. Layfield's testimony, however, did not end with these two questions and answers. In fact, in response to the very next question, he agreed that he could not testify that Daniel did not already have a cancerous tumor when she began taking Prempro:

> Q. Tell me what basis you could possibly have to know that at the point in time where she started her hormone therapy she doesn't already have an occult breast cancer. And I'm talking about the woman at issue in this case. How can you rule that out?
>
> A. I cannot exclude that she had an occult breast cancer –
>
> Q. Okay.
>
> A. -- at the time.

Id. at 94-95.

Moreover, on cross-examination, Dr. Layfield further clarified his lack of certainty with respect to the cause of Daniel's breast cancer:

> Q. Okay, but as we sit here, you don't know whether it was there – whether it was she already had cancer and the hormone therapy caused it to grow or proliferate and be detected; is that right? That's certainly a possibility.
>
> A. That's one possibility.
>
> Q. That is a possibility. And another possibility is that she had a DCIS, and that that was caused to proliferate?
>
> A. Proliferate, and by proliferation, picked up the additional characteristics of invasion with the potential for metastasis.
>
> Q. But again, as between those two, there was no test or marker that allowed you to pick one or the other?
>
> A. Not that I'm aware of.
>
> Q. Okay. And it could just as easily be that she had, you're saying, some type of atypical hyperplasia

> which then proliferated and became a cancer. Is that you're saying [sic]?
>
> A. That's correct.
>
> Q. So it could be any of those three possibilities?
>
> A. Any one of those three possibilities.
>
> Q. And I am correct that you can't say, as we sit here today, that one is more likely than the other?
>
> A. Not on the basis of review of those slides, no . . .
>
> Q. Okay. Now Doctor, we've already agreed you have no idea as we sit here today whether she started with an occult cancer, a hyperplasia or a DCIS, right?
>
> A. That is correct.

Id. at 108-109.

Finally, Dr. Layfield testified that he was familiar with the results of the WHI study and agreed that this study showed no statistical increase in breast cancer until the patient had taken Prempro for four to five years:

> Q. All right. And did you look at the WHI article at all, the one on [Prempro], not the [Premarin] only?
>
> A. Women's Health Initiative?
>
> Q. Yes?
>
> A. Yes, yes, I did.
>
> Q. And you saw in that the statistically significant increase in breast cancer didn't occur until – it started – may be started to see a little blip at year four and then at year five, there was an increase in incidence?

A. Yes, I saw that.

Q. All right. But you would agree with me that whatever it was, she did not take this for a very long time?

A. She took it for, by the records, 18 months.

Q. Every other day?

A. Every other day.

Q. So it's half the normal dose, half the dose that's recommended?

A. That's correct.

Id. at 108-109.

Taken as a whole, then, Dr. Layfield's deposition testimony – all of which was read to the jury – may fairly be summarized as follows:

- Daniel's condition at the time she began ingesting Prempro consisted of one of three possibilities: (1) a premalignant lesion, or atypical hyperplasia, that Prempro caused to proliferate and develop into cancer; (2) an occult (hidden) cancer that Prempro caused to proliferate and eventually (after sufficient growth) be detected; or (3) a ductal carcinoma in situ ("DCIS") that Prempro caused to proliferate and, by proliferation, picked up the additional characteristics of invasion with the potential for metastasis;

- Dr. Layfield had no basis on which to determine which of these three possibilities (occult cancer, atypical hyperplasia, or DCIS), and he could not testify that any one of these three possibilities was any more likely than the other two; and

- The WHI study provided him with no epidemiological evidence on which to arrive at any firm opinions with

> regard to Daniel's condition, particularly in light of her short-term use of a half dose of the drug.

At his deposition in the ***Zandi*** case four months later, Dr. Layfield was asked about his prior testimony in the Daniels' case. The record does not reflect that he reviewed (or was asked to review) the transcript of his deposition in the Daniel's case. He nevertheless offered the following testimony:

> Q. You were, as you mentioned, involved in the Daniels' case. What was the reason you didn't appear live as a witness in that case?
>
> A. My issue was that there was no more than 18 months between the mammo – well, actually, the resection of the cancer and her initiation of the hormone therapy, and I was concerned that was a very short time.
>
> Q. So in the Daniels' case you thought that Ms. Daniel, more likely than not, didn't have cancer related to hormone therapy because her duration of use was so short?
>
> A. Let me phrase this correctly. I felt that more likely than not she had at least one of the late-stage lesions, meaning atypical intraductal hyperplasia or ductal carcinoma in situ.
>
> And my concern was that if she had ductal carcinoma in situ, which I could not say with a reasonable degree of medical certainty that she didn't have, because it's just 18 months, right, and there was a radiograph that was maybe even briefer than that, as I recall, that if she had had, at the time she commenced hormonal therapy, a small invasive cancer, it wouldn't have mattered, in my mind. It would have grown a bit faster, but it would not have affected what had to be done.

Q. She would have had the same treatment regardless?

A. That was my opinion.

Q. Okay. And so you shared with Plaintiff's counsel after your deposition that you were concerned that the duration of use would mean to you that you really couldn't give an opinion that her cancer was caused by hormone therapy?

A. To a reasonable degree of medical certainty, that would be correct.

* * *

Q. And then they decided not to call you, or did you ask not to be called?

MR. MEADOWS: Objection

A. I said that all I was comfortable with testifying in her case was that she had a cancer that was well-differentiated to moderately differentiated, that it had these Ki-67 values, but I did not feel sufficiently certain that she did not have either preexisting cancer in that short period of time or that she didn't have DCIS as the lesion.

Q. (By Ms. Moos) And so you couldn't give an opinion on cause?

A. That's correct.

Zandi case at 150-52.

Comparing Dr. Layfield's ***Zandi*** testimony with his deposition testimony read to the jury in this case, it is clear that there was no recantation. To the contrary, the testimony in both depositions was remarkably consistent. In both instances, he testified that that the short

duration of her use of Prempro precluded any use of the WHI study results to buttress a causation finding, and that he had no basis to determine whether Daniel had a pre-existing occult cancer, a DCIS, or a pre-malignant lesion induced through proliferation to become cancerous. In both depositions, Dr. Layfield testified unambiguously that he while he could say that Daniel had a cancerous tumor in her breast, and that the Prempro (based on the Ki-67 results) had caused it to grow, he could not testify as to *what* the Prempro had caused to grow (a pre-malignant hyperplasia, a DCIS, or an occult malignant tumor).

The trial court's attempts to distinguish Dr. Layfield's testimony at the two depositions reflects a failure to read the entirety of the testimony at either deposition. The trial court points out that "Dr. Layfield does not reconcile his Daniel testimony that it was at most a 'possibility' that Daniel already had a late-stage lesion when she started taking hormone therapy to believing it was 'more likely than not.'" Trial Court Opinion, 9/24/08, at 13. In the Daniel deposition, however, Dr. Layfield described all three potential conditions at the time she began taking Prempro as "possibilities," not just the "late stage lesions" (which the trial court apparently thought referred to occult cancers). In the ***Zandi*** deposition, Dr. Layfield made clear that by "late stage lesions" he was referring to "atypical intraductal hyperplasia or ductal carcinoma in situ," and not pre-existing cancer (although shortly thereafter he included "preexisting cancer" as a third possibility). In both

depositions, Dr. Layfield consistently and without exception refused to opine that either of the three possible conditions existed at the time Daniel began to take Prempro – only that it had to be one of the three. As a result, there was nothing for Dr. Layfield to reconcile.

Similarly, the trial court also noted that "[Dr. Layfield] does not reconcile the trial testimony that hormone therapy caused the transformation of a pre-existing, non-malignant lesion to invasive cancer with his ***Zandi*** testimony that, at most, hormone therapy caused an already existing cancerous tumor to 'grow[] a little faster.'" ***Id.*** Again, however, reviewing the entirety of Dr. Layfield's testimony as read to the jury, he simply did not testify that the ingestion of Prempro caused a pre-malignant lesion to proliferate into a cancerous tumor. Instead, he testified that this was merely one possibility (among the three expressly specified). If this was not entirely clear to the jury during the reading of Dr. Layfield's testimony, counsel for Wyeth emphasized it during closing arguments: "And that's why Dr. Layfield, himself, after all of this testing, said I can't exclude the possibility that she had an occult or hidden breast cancer on the earlier occasion before she ever took hormone therapy." N.T., 1/25/07 (AS), at 120.

Finally, the trial court found that "Dr. Layfield's affidavit does not explain why he was unable to appear live at the Daniel trial," and that "Although Dr. Layfield confirmed in the ***Zandi*** deposition that he had

informed Plaintiff's counsel of his revised opinion, he subsequently denies that any conversations took place." Trial Court Opinion, 9/24/08, at 12-13. Dr. Layfield's decision not to appear in person to testify at the Daniels' trial was, of course, not Dr. Layfield's but rather that of counsel for the Daniels, and the reason for not doing so is plain from both deposition transcripts – Dr. Layfield repeatedly made clear that he could not offer any expert opinion on causation to a reasonable degree of medical certainty, since he could not opine as to whether Daniel had an occult cancer, a DCIS, or an atypical hyperplasia when she began taking Prempro.[8] We further note that in his affidavit, Dr. Layfield did not deny "that any conversations took place" with counsel regarding testifying at trial.[9] Instead, in his affidavit Dr. Layfield

[8] Dr. Layfield's deposition testimony was obviously read to the jury primarily (if not exclusively) so that the results of the Ki-67 could be presented to the jury and relied upon by other experts (including Dr. Naftalis, the Daniels' principal expert on causation). Given our conclusion regarding the lack of recantation by Dr. Layfield on causation issues, it is not necessary to review the trial court's findings regarding Dr. Naftalis' testimony in detail (including whether Dr. Layfield's causation testimony was cumulative of Dr. Naftalis' causation testimony). We note, however, that the trial court's finding that Dr. Naftalis based some or all of her causation opinions on the results of Dr. Layfield's Ki-67 tests does not provide grounds for a new trial – in substantial part because not even the trial court found that Dr. Layfield ever recanted his testimony regarding his Ki-67 tests. As such, there is no basis for concluding that Dr. Naftalis based her causation opinions on recanted testimony.

[9] With regard to Dr. Layfield's affidavit, we further conclude that Judge Tereshko erred in concluding that it was his function to assess its credibility. Judge Tereshko did not observe Dr. Layfield testify, either in this case or in the ***Zandi*** case, and therefore had no basis upon which to assess his credibility. Instead, here it was the trial court's function to review Dr.

merely denied "that I recanted any of my deposition testimony." Affidavit of Lester J. Layfield, M.D., at ¶ 7. Based upon the foregoing, this averment was truthful.

For these reasons, we reverse the trial court's order dated August 24, 2007 granting Wyeth a new trial. As explained hereinabove, we conclude that no basis exists in the record on appeal to support Wyeth's contention that Dr. Layfield recanted his testimony in this case in his subsequent deposition in the ***Zandi*** case. Contrary to Wyeth's contentions in its supplemental motion for post-trial relief, no "fraud on the court" took place here and a new trial should not have been granted on this basis.

Accordingly, we will proceed to consider the issues raised in Wyeth's cross-appeal. For its first issue, Wyeth contends it is entitled to a new trial because the trial court erred in permitting the Daniels to introduce evidence of subsequent remedial measures in the form of warnings that post-dated Daniel's use of the drug to prove negligence. Wyeth argues that "post-use, post-injury, post-WHI warnings were inadmissible pursuant to Pa. R. Evid. 403 and 407, as well as case law interpreting those rules." Brief of Appellees at 31.

Layfield's affidavit to determine if it adequately explained any material differences in his deposition testimony in the two cases. Of course, the best source for determining whether the depositions were contradictory were the transcripts of the depositions.

We conclude that Wyeth failed to preserve this issue for appeal. In its appellate brief, Wyeth notes that it filed a motion *in limine* objecting to "any use of post-use labeling, but the motion was denied." ***Id.*** at 30. Our review of the record reflects a different history on this point. During pre-trial argument on Wyeth's motion *in limine* on January 3, 2007, counsel for the Daniels argued that they intended to use the post-WHI label (hereinafter, the "2005 label") for the limited purpose of showing proximate causation. Specifically, counsel for the Daniels represented that if Wyeth had done the necessary studies on the cancer risk posed by Prempro earlier, the warning label that Daniel's doctor (Dr. Haggard) saw before prescribing the drug to her would have looked substantially similar to the 2005 label (*i.e.*, with a "black box that has the definitive language"). N.T., 1/3/07 (AS), at 79. In response, counsel for Wyeth contended that Dr. Haggard could confirm the importance of more significant warnings without counsel for the Daniels actually showing the jury the 2005 label, and further recommended that the trial court adopt the approach taken by the trial judge in a similar case[10] – in which the trial judge "reserved on the issue until they had the opportunity to hear at trial from the doctor about whether that would have made a difference to the doctor." ***Id.*** at 80-81.

[10] ***Nelson v. Wyeth Pharmaceuticals, Inc.***, 2010 WL 1223049 (Pa. March 30, 2010).

The trial court apparently agreed with Wyeth's recommendation, as it entered an order dated January 11, 2007 granting Wyeth's motion *in limine* in part. In a handwritten notation on the order, the trial court indicated that "Plaintiff may use the 2005 label in presenting its case and has presented evidence from a doctor as to whether or not it would have made a difference." Order Regarding Wyeth's Motion *in Limine* No. 10 at 1. While this handwritten notation is not the model of clarity, in the context in which it was entered, it is clear that the Daniels' use of the 2005 label was limited to causation testimony by Dr. Haggard, and only after he testified that a "black box" label would have made a difference to him. With this limited exception, the trial court's decision to otherwise *grant* the motion *in limine* clearly reflects that any other use of the 2005 label, including any attempt to use it to prove negligence, was prohibited.

On appeal, Wyeth does not seem to take issue with the trial court's decision to allow the use of the 2005 label in connection with Dr. Haggard's testimony. To the contrary, in its appellate brief Wyeth points out that "Daniel did not even call Dr. Haggard to testify at trial and, in his deposition, did not ask him whether the post-use labeling would have altered his prescribing of the drug for her." Brief of Appellees at 33. In any event, we do not conclude that the trial court's decision to allow the use of the 2005 label for the limited purpose of demonstrating proximate causation through

Dr. Haggard's testimony was error.[11] ***See, e.g.***, ***Brazos River Authority v. GE Ioncis, Inc.***, 469 F.3d 416, 429 (5th Cir. 2006) (the federal counterpart to Pa.R.E. 407, "subsequent remedial measures can be introduced on the issue of causation if that issue is in controversy"); ***see also Wetherill v. Univ. of Chicago***, 565 F. Supp. 1553, 1558 (N.D. Ill. 1983) (same).

Instead, Wyeth contends that "counsel's rationale was a pretext for placing the two warnings side by side in order to argue from the contrast that the earlier breast cancer warning was inadequate." Brief of Appellees at 33. In this regard, Wyeth identifies four occasions on which counsel for the Daniels used the 2005 label to prove negligence by demonstrating the inadequacy of the prior label, including during the testimony of Dr. Michael Dey, Cheryl Blume, Ph.D, and in both opening and closing arguments. N.T. 1/9/07 (AS) at 40, 52-54; 1/10/07 (AS) at 56-62; 1/25/07 (AS) at 41-42. On these occasions, Wyeth contends that "Daniel's counsel made the post-

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[11] Pennsylvania Rule of Evidence 407 provides as follows:

> When, after an injury or harm allegedly caused by an event, measures are taken which, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove that the party who took the measures was negligent or engaged in culpable conduct, or produced, sold, designed, or manufactured a product with a defect or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for impeachment, or to prove other matters, if controverted, such as ownership, control, or feasibility of precautionary measures.

Pa.R.E. 407.

use warnings the centerpiece of her liability case, arguing right from the start that the post-use warnings demonstrated the inadequacy of the warnings provided in the 1999 labeling." Brief of Appellees at 31.

To the extent that counsel for the Daniels used the 2005 label in attempts to prove Wyeth's negligence in this case, this use was prohibited by the trial court when it granted Wyeth's motion *in limine* in part. As such, a timely and contemporaneous objection was required to provide the trial court with an immediate opportunity to issue an appropriate ruling.[12] ***See, e.g.***, ***Commonwealth v. Rivera***, 603 Pa. 340, 370, 983 A.2d 1211, 1229 (2009), *cert. denied*, 130 S.Ct. 3282 (2010); ***Criswell v. King***, 575 Pa. 34, 40, 834 A.2d 505, 508-09 (2003). Based upon our review of the voluminous record on appeal, however, counsel for Wyeth did not assert any objection to the Daniels' use of the 2005 label during trial, including on the four specific instances where it now asserts that the evidence was used contrary to the trial court's ruling on the motion *in limine*. Issues not raised by timely objection at trial are waived for purposes of appeal. Pa.R.A.P. 302; ***Dilliplaine v. Lehigh Valley Trust Co.***, 457 Pa. 255, 258-59, 322 A.2d 114, 116-17 (1974).

[12] Although Wyeth points out that it raised this issue in its post-trial motion for a new trial, Brief of Appellees at 30 n.17, this did not preserve it for appeal. Pursuant to Pa.R.C.P. 227.1(b)(1)(Note), post-trial relief is not available when the error could have been corrected if it had been raised by timely objection during trial. ***See also id.*** (Explanatory Comment – 1983) ("the grounds for the post-trial relief requested must have been raised in pre-trial proceedings or at trial").

For its second issue presented in its cross-appeal, Wyeth argues that the trial court erred in not granting its motion for judgment notwithstanding the verdict ("JNOV") on proximate causation. Wyeth contends that the Daniels did not present any evidence that a different breast cancer warning would have caused Dr. Haggard not to proscribe Prempro for her. Brief of Appellees at 34. The parties here agree that to prove proximate causation under the learned intermediary doctrine in this case, Daniels needed to present sufficient evidence to establish "a reasonable inference that Dr. Haggard would have changed his prescribing decision" if presented with an adequate warning. Brief of Appellees at 35; Reply Brief of the Appellants at 27.

Our standard of review for an order denying judgment notwithstanding the verdict is whether there was sufficient competent evidence to sustain the verdict. ***Whitaker v. Frankford Hosp. of City of Philadelphia***, 984 A.2d 512, 517 (Pa. Super. 2009). With respect to questions of law, our scope of review is plenary. ***Underwood ex rel. Underwood v. Wind***, 954 A.2d 1199, 1206 (Pa. Super. 2008). Any conflict in the evidence must be resolved in favor of the verdict winner's favor. ***Eichman v. McKeon***, 824 A.2d 305, 311 (Pa. Super.), *appeal denied*, 576 Pa. 712, 839 A.2d 352 (2003). If any basis exists upon which the jury could have properly made its award, then we must affirm. ***Griffin v. University of Pittsburgh***

Medical Center-Braddock Hosp., 950 A.2d 996, 999 (Pa. Super. 2008), *appeal denied*, 601 Pa. 680, 970 A.2d 431 (2010).

In ***Simon v. Wyeth Pharmaceuticals, Inc.***, 989 A.2d 356 (Pa. Super. 2009), this Court reaffirmed that proximate cause is an essential element in failure to warn cases involving prescription medications. ***Id.*** at 368. Pennsylvania law requires that "there must be some reasonable connection between the act or omission of the defendant and the injury suffered by the plaintiff." ***Demmler v. SmithKline Beecham Corp.***, 671 A.2d 1151, 1155 (Pa. Super.), *appeal denied*, 546 Pa. 655, 684 A.2d 557 (1996). In this context, the plaintiff must establish that if defendant "had issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." ***Id.***

In failure to warn cases involving pharmaceutical drugs,[13] Pennsylvania applies the learned intermediary doctrine:

> [T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose

[13] As this Court recently clarified, as a result of the inherent risks and dangers associated with prescription drugs, a plaintiff who alleges a strict liability cause of action against a drug manufacturer is limited to two available causes of action: (1) a manufacturing claim, or (2) a failure to warn claim. ***Lance v. Wyeth***, 2010 WL 2991597 at *4 (Pa. Super., August 2, 2010) (citing ***Baldino v. Castagna***, 478 A.2d 807, 810 (Pa. Super. 1984)). If a plaintiff asserts a failure to warn claim, strict liability will not be imposed upon the drug manufacturer, and instead the claim will be analyzed and adjudicated in accordance with the negligence standard contained in the Restatement (Second) of Torts, § 388. ***Id.*** (citing ***Hahn v. Richter***, 543 Pa. 558, 562, 673 A.2d 888, 890-91 (1996)).

> use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Taurino v. Ellen, 579 A.2d 925, 927 (Pa. Super. 1990), *appeal denied*, 527 Pa. 603, 589 A.2d 693 (1991) (quoting ***Makripodis by Makripodis v. Merrell-Dow Pharmaceuticals, Inc.***, 523 A.2d 374, 378 (Pa. Super. 1987)).

At trial in the case *sub judice*, Dr. Haggard testified that it was his practice when prescribing hormone therapy drugs to engage in a discussion of the benefits and the risks with the patient, and to allow the patient to make the final decision on whether to take the drugs. N.T., 1/17/07 (AS),

at 25. Dr. Haggard further testified that when he prescribed Prempro to Daniel, he warned her of certain risks (e.g., headaches, nausea, vaginal bleeding), but not of the risk of cancer. ***Id.*** at 10, 17. He stated that in his view the physician's package insert did not, at the time he prescribed Prempro to Daniel, provide him with any basis to conclude that the drug posed any significant risk of breast cancer to her, since its warnings in this regard appeared to be limited to cases of higher doses or doses for a prolonged period of time (ten years or more). ***Id.*** at 27. Finally, Dr. Haggard testified that if he had seen a "black box-type" breast cancer warning similar to that later set forth on the post-WHI study package inserts, he would have passed this information along to Daniel and emphasized it during their discussions regarding the risks associated with taking the drug. ***Id.*** at 35.

Daniel testified that Dr. Haggard never informed her of the risk of breast cancer from taking Prempro, and that if she had known of the risk of breast cancer associated with Prempro, she would not have taken the drug – even if Dr. Haggard had recommended it. N.T., 1/17/07 (MS), at 28-29. Daniel also testified that she read the warnings on the patient information sheets that accompanied her monthly supply of Prempro pills, and that nothing contained therein made her believe that taking the drug would cause her to develop breast cancer. ***Id.*** at 32. She emphasized that if any

of these information sheets had contained a "black box" warning about breast cancer, she would not have taken the drugs. ***Id.***

In ***Simon***, this Court reversed a trial court's grant of JNOV on proximate causation in a failure to warn case involving HRT medications (including Prempro). Reviewing testimony in that case substantially similar in all material respects to that presented here, we determined that sufficient evidence existed to permit the jury to believe the testimony of the plaintiff's doctors "that they would have permitted [plaintiff] to decide, based on the cancer risk that the WHI study revealed, whether to accept prescriptions for HRT." ***Id.*** at 375. We concluded that the jury in ***Simon*** was entitled to believe the plaintiff's testimony that "based upon the WHI study findings, she would not have utilized HRT once her doctors communicated the information they presently share with patients regarding breast cancer risks." ***Id.*** Accordingly, viewing the evidence in the light most favorable to the verdict winner and giving the plaintiff every reasonable inference of fact, this Court concluded that the plaintiff in that case had sustained her burden of proof on proximate causation and that it was error to grant JNOV on that issue. ***Id.*** at 376.

Based upon our review of the testimony of record here as well as our reasoning in ***Simon***, we conclude that the trial court did not err in refusing to grant JNOV in favor of Wyeth on the proximate causation issue. Sufficient evidence of record exists in this case permitting the jury to find that if Wyeth

had issued adequate warnings regarding the risk of breast cancer, Dr. Haggard would have altered his prescribing practices for Prempro (by specifically advising Daniel of the risk of breast cancer), and Daniel's injury would have been avoided since Daniel would have declined the prescription.

For its third issue presented in its cross-appeal, Wyeth argues that the trial court erred in not granting JNOV in its favor because the Daniels did not offer any expert medical testimony that Wyeth's warnings to physicians were not adequate. Wyeth contends that the only expert witness who opined that Wyeth's labeling inadequately warned physicians of the risk of breast cancer from Prempro was Cheryl Blume, Ph.D. As Wyeth points out, Dr. Blume is not a medical doctor, has never practiced medicine, and has no medical specialty relevant here to the use of HRT drugs, including neither gynecology nor oncology. Brief of Appellees at 37.

Rule 702 of the Pennsylvania Rules of Evidence provides no particular rules for the qualification of experts. Instead, pursuant to Rule 702 an expert may be qualified to testify so long as he or she has "scientific, technical or other specialized knowledge beyond that possessed by a layperson" that will in some manner assist the jury in understanding the evidence presented. Whether or not an expert witness is qualified to testify is usually a matter left to the sound discretion of the trial court. ***See, e.g.***, ***Jacobs v. Chatwani***, 922 A.2d 950, 956 (Pa. Super.), *appeal denied*, 595 Pa. 708, 938 A.2d 1053 (2007).

Wyeth relies primarily upon two decisions from this Court in support of its position that Pennsylvania law requires that only physicians may opine as to the adequacy of a drug's warning. First, in ***Demmler v. SmithKline Beecham Corp.*** we stated that "[g]enerally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect." ***Id.*** at 1152. We find Wyeth's reliance on ***Demmler*** in this regard to be unpersuasive for two reasons. First, to the extent that this quoted language in ***Demmler*** purports to require that only medical experts may testify regarding the adequacy of drug labeling, it is mere *obiter dicta*, as the issue of whether a physician must testify regarding the adequacy of drug label warnings was never at issue in that case. In ***Demmler***, a physician testified on behalf of plaintiff regarding the alleged inadequacy of the drug label, and thus whether the issue of whether *only* a physician could do so never arose for our consideration. ***Id.***

Second, the quoted language in ***Demmler*** only requires that a plaintiff offer the testimony of a "medical expert" on the adequacy of warning labels, and does not specify that the medical expert be a licensed physician. Sufficient evidence of record existed to permit the trial court to find that Dr. Blume qualified as a satisfactory "medical expert," as that term was used in ***Demmler***. Her testimony disclosed that she had a Bachelors degree in

Biology and a Doctoral degree in Medical Pharmacology and Toxicology. N.T., 1/10/07 (MS), at 36. Dr. Blume further testified that in her twenty-year career as an executive with a major pharmaceutical company (Mylan Laboratories), she had been responsible for securing FDA approval of over 100 prescription drugs, and that her responsibilities included revising drug labels in light of post-marketing safety signals. ***Id.*** at 38-42. Based upon this testimony, the trial court aptly noted that as a "labeling expert," Dr. Blume was arguably "more qualified than a doctor who deals very marginally with these issues." N.T., 1/18/07 (AS), at 83.

Wyeth also relies upon ***Dion v. Graduate Hospital of University of Pennsylvania***, 520 A.2d 876 (Pa. Super. 1987), in which we affirmed a trial court's grant of a non-suit because the plaintiff did not introduce expert testimony on the adequacy of the drug's warning label, and, in general, "only physicians *or others with similar education and experience regarding prescription drugs* would be qualified to testify as to the adequacy of the warning." ***Id.*** at 879 (emphasis added). Rather than requiring a physician to provide such expert testimony, in ***Dion*** this Court expressly recognized that any expert "with similar education and experience" to a physician is qualified to opine on the adequacy of a drug's warning label. Based upon her qualifications as set forth, the trial court did not err in finding that Dr. Blume was qualified to offer testimony regarding the adequacy of Wyeth's warning label in this case.

For the fourth and final issue in its cross-appeal, Wyeth argues that the trial court erred in not granting JNOV in its favor because the Daniels presented no evidence that the short-term use of Prempro caused Daniel's breast cancer. Wyeth contends that the Daniels' experts (except for Dr. Naftalis) conceded that there were no studies that demonstrate that the use of Prempro for less than two years increases the risk of breast cancer, and that the only study cited by Dr. Naftalis had not been published at the time of trial. Brief of Appellees at 38-40. Accordingly, because Daniel took Prempro for only 18 months before being diagnosed with breast cancer, Wyeth contends that the Daniels failed to prove general causation. ***Id.*** at 42.

As explained hereinabove, our standard of review when reviewing the denial of a motion for JNOV, we must view the evidence in the light most favorable to the verdict winner and give that party the benefit of every reasonable inference arising therefrom. Furthermore, in so doing we must reject all unfavorable testimony and inferences and carefully avoid the substitution of our judgment for that of the finder of fact. Given this standard of review, we conclude that the Daniels presented sufficient evidence that the short term use of Prempro increases the risk of breast cancer.

For example, the Daniels introduced the testimony of Dr. Donald Austin, an epidemiologist, who opined that in some women the effects from Prempro would be seen within months rather than years:

> Q. … Tell us the amount of time you would expect from the time the woman starts taking the E plus P therapy and when you can see a cancer caused by the promotion effect of those drugs in a woman?
>
> A. Well, there is going to be a bell-shaped curve for women. If you put a thousand women on it, some will get it very quickly and some will not get it until two or three or four or five years later. But you start seeing the effect almost immediately.
>
> Q. Would that be within months, years, what?
>
> A. Well, yes, as soon as the tumor is large enough to be picked up clinically.
>
> Q. So in terms of the promoter effect, is it the same sort of timeframe as you would expect to see with uterine or endometrial cancer?
>
> A. Yes.
>
> Q. And that would be months?
>
> A. Yes.

N.T., 1/16/07 (AS), at 11.

Dr. Elizabeth Naftalis, a surgeon specializing in breast cancer, served as the Daniels' primary causation witness, offering both general causation opinions as well as specific ones related to Daniel's breast cancer. For her general causation opinions, Dr. Naftalis expressly agreed with the opinion of Dr. Graham Colditz, a cancer researcher from Harvard University, that

Prempro may promote abnormal cells into breast cancer within six months to one year. N.T., 1/17/07 (MS), at 41. She also testified that she relied upon an epidemiological study performed by Dr. Peter Ravdin, which reported that after the number of women taking the combination of estrogen and progestin decreased sharply in July 2002 (after publication of the WHI study), the number of breast cancer cases reported over the next six to eighteen months (through the end of 2003) was 15,000 less than expected. N.T., 1/12/07 (AS), at 9.

In addition, with respect to Daniel specifically, Dr. Naftalis testified affirmatively that Daniel's 18-month use of Prempro caused her breast cancer:

> Q. Is it your view and your opinion that prior to December, 1999, at her first use of Prempro, Ms. Daniel did not have any tumor of any size at all?
>
> A. That's correct.
>
> * * *
>
> Q. What is the basis for your certainty under oath that she did not have a tumor prior to the time she started taking Prempro?
>
> A. It's based on my review of the records, my education, my experience and the most recent data that's come out showing us that 6 to 18 months off of hormone therapy, you see a decreased risk in breast cancer.

N.T., 1/12/07 (AS), at 73-74. Dr. Naftalis also testified that she relied in part on the Ki-67 tests performed by Dr. Layfield. N.T., 1/12/07 (MS), at

97, 107 ("The evidence clearly points to the fact that her intake of combination hormone therapy caused her breast cancer in this particular case.").

We recognize that on cross-examination these experts conceded significant points, including the general lack of published and peer-reviewed studies demonstrating a statistically significant increase in the risk of contracting breast cancer after taking Prempro for less than two years.[14] In this regard, the experts called by the Daniels (including Dr. Layfield) also acknowledged that the WHI study conducted by the NIH found no increased risk of breast cancer after using Prempro for two years or less. ***See, e.g.***, N.T., 1/16/07 (AS), at 30; N.T., 1/12/07 (AS), at 16. Given our standard of review in connection with a motion for JNOV, however, it was for the jury to evaluate the testimony of these experts based on both their direct testimony and cross-examination, and to resolve any inconsistencies or weaknesses in their testimony when deciding the facts of the case. In reviewing a denial of a motion for JNOV, conflicts in the evidence must be settled in the favor of the verdict winner (here, the Daniels). Because Drs. Austin and Naftalis both testified that the short-term use of Prempro may result in breast

[14] In its appellate brief, Wyeth points out that Dr. Ravdin's study was not published at the time of trial, but that it was subsequently published thereafter. Appellee's Cross-Appeal Reply Brief at 12-13 & n.5 (citing to Peter M. Ravdin, *et al.*, *The Decrease in Breast-Cancer Incidence in 2003 in the United States*, 356 N. Eng. J. Med. 1670, 1673 (April 19, 2007)).

cancer, the trial court did not err in refusing to grant Wyeth's JNOV motion on this issue.

Finally, we turn to the trial court's grant of Wyeth's JNOV motion on the availability of punitive damages in this case. The trial court ruled in Wyeth's favor for two reasons. First, the trial court found "no evidence from which a reasonable juror could find reckless and outrageous conduct, allowing all inferences in favor of the plaintiffs." Trial Court Opinion, 4/23/07, at 2. Second, the trial court ruled that federal constitutional law precludes a state court from awarding punitive damages based on out-of-state conduct (in this case, events occurring in Arkansas). ***Id.*** at 5 (quoting ***BMW of North America, Inc. v. Gore***, 517 U.S. 559 (1996)). We address these two points in turn.

Both the Daniels and Wyeth agree that the appropriate legal standard for evaluating an award of punitive damages in Pennsylvania is set forth in ***Hutchison ex rel. Hutchison v. Luddy***, 582 Pa. 114, 870 A.2d 766 (2005).[15] Our Supreme Court in ***Hutchinson*** offered the following review of Pennsylvania law on punitive damages:

[15] The trial court did not charge the jury in accordance with the specific requirements for an award of punitive damages as set forth in ***Hutchinson***. Instead, the trial court charged the jury consistently with the more general instruction (No. 14.00) of the Pennsylvania Suggested Standard Civil Jury Instructions. While Wyeth asked at the charging conference that the standard charge be supplemented with language from Restatement (Second) of Torts § 500, N.T., 1/25/07 (MS), at 107-08 (referencing ***Phillips v.***

> The standard governing the award of punitive damages in Pennsylvania is settled. "Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." As the name suggests, punitive damages are penal in nature and are proper only in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct. The purpose of punitive damages is to punish a tortfeasor for outrageous conduct and to deter him or others like him from similar conduct. Additionally, this Court has stressed that, when assessing the propriety of the imposition of punitive damages, "[t]he state of mind of the actor is vital. The act, or the failure to act, must be intentional, reckless or malicious."
>
> In [***Martin v. Johns-Manville Corp.***, 508 Pa. 154, 494 A.2d 1088 (1985) (plurality opinion)], this Court considered the requisite state of mind which would constitute reckless indifference in this context, and we set forth the standard the courts are to apply when called upon to determine whether the evidence supports a punitive damages award on such a basis. Noting that Comment b to Section 908(2) of the Restatement refers to Section 500 as defining the

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Cricket Lighters, 584 Pa. 179, 883 A.2d 439 (2005)), neither party appears to have requested a jury instruction consistent with ***Hutchinson***.

In their appellate briefs filed with this Court, however, both the Daniels and Wyeth insist that the principles in ***Hutchinson*** should guide our analysis. Brief of Appellants' at 46; Brief of Appellee at 47-48. Accordingly, we will proceed on that basis, in part because neither party has challenged any aspect of the jury charge. In this regard, we note that the record on appeal does not contain either the points for charge submitted by the parties or the transcript of the oral argument on January 30, 2007 prior to the trial court's grant of Wyeth's JNOV motion. As such, our understanding of the trial court's decision for charging the jury as it did on punitive damages and/or the legal standards on which it initially based its decision to grant Wyeth's JNOV motion, is lacking. In its written opinion supporting its decision, however, the trial court cites to, and relies upon, ***Hutchinson***.

requisite state of mind for punitive damages based on reckless indifference, this Court turned to Section 500, which states:

> § 500 Reckless Disregard of Safety Defined
>
> The actor's conduct is in reckless disregard of the safety of another if he does an act or intentionally fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.

Restatement (Second) of Torts § 500

Noting that Section 500 sets forth two very different types of state of mind as to reckless indifference, ***Martin*** stated that the first is "where the 'actor knows, or has reason to know, ... of facts which create a high degree of risk of physical harm to another, and deliberately proceeds to act, or to fail to act, in conscious disregard of, or indifference to, that risk;' " and that the second is "where the 'actor had such knowledge, or reason to know, of the facts, but does not realize or appreciate the high degree of risk involved, although a reasonable man in his position would do so.'" ***Martin*** recognized that the first type of reckless conduct described in Section 500 "demonstrates a higher degree of culpability than the second on the continuum of mental states which range from specific intent to ordinary negligence[,]" because "[a]n 'indifference' to a known risk under Section 500[,] is closer to an intentional act than the failure to appreciate the degree of risk from a known danger."

The ***Martin*** Court then stated that "[u]nder Pennsylvania law, only the first type of reckless conduct described in comment a to Section 500, is

> sufficient to create a jury question on the issue of punitive damages [,]" rejecting as insufficient the second type of recklessness, which is premised on a "reasonable man standard." In other words, this Court concluded that "an appreciation of the risk [of harm] is a necessary element of the mental state required for the imposition of [punitive] damages." In this regard, we reasoned that:
>
> > The only purpose of punitive damages is to deter outrageous conduct. It is impossible to deter a person from taking risky action if he is not conscious of the risk. Thus, in ***Feld v. Merriam***, 506 Pa. 383, 485 A.2d 742 (1984), we addressed the issue of when punitive damages are warranted and stressed that, in determining whether certain conduct is outrageous, "[t]he state of mind of the actor is vital. The act, or the failure to act, must be intentional, reckless or malicious." Similarly, the Restatement explains that "reckless indifference to the rights of others and conscious action in deliberate disregard of them ... may provide the necessary state of mind to justify punitive damages." Therefore, an appreciation of the risk is a necessary element of the mental state required for the imposition of such damages.
>
> Thus, in Pennsylvania, a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.

Id. at 121-24, 870 A.2d at 771-72 (citations and footnotes omitted); ***see also Phillips***, 584 Pa. at 188, 883 A.2d at 445 (2005) ("[P]unitive damages are an 'extreme remedy' available only in the most exceptional

circumstances."); ***Doe v. Wyoming Valley Health Care System, Inc.***, 987 A.2d 758, 768 (Pa. Super. 2009).

Based upon this legal standard, the trial court granted Wyeth's JNOV motion, finding as follows:

> [The Daniels] did not present sufficient evidence for a juror to find that Wyeth had a subjective appreciation of the risk of harm to which [Daniel] was exposed. There was simply no evidence that Wyeth knew that additional studies were necessary given the great body of scientific literature on hormone replacement therapy and the lack of an appreciable risk of harm for short-term users of Prempro. Wyeth consistently complied with FDA requests to conduct appropriate testing. Wyeth's 'failure' to conduct additional studies was therefore not intentional nor in reckless disregard of the health of short-term Prempro users, as the test in ***Hutchinson***, ***supra*** requires.
>
> There was no evidence introduced at trial that Wyeth's conduct with regard to Prempro was outrageous, because of an evil motive, or in reckless disregard to patient safety. To the contrary, the admissions of [the Daniels'] own experts established that Wyeth complied with all federal regulations regarding the testing and labeling for Prempro and at all times provided warnings regarding the risk of breast cancer that were consistent with extant science.

Trial Court Opinion, 4/23/07, at 4. As explained in detail above, we review the trial court's grant of JNOV to determine whether there was sufficient competent evidence to sustain the jury's verdict. ***Brown v. Progressive Insurance Co.***, 860 A.2d 493, 497 (Pa. Super. 2004) (citing ***Birth Center v. St. Paul Companies, Inc.***, 567 Pa. 386, 397, 787 A.2d 376, 383

(2001)), *appeal denied*, 582 Pa. 714, 872 A.2d 1197 (2005). To affirm a grant of JNOV, the evidence must be "such that no reasonable minds could disagree that the moving party is entitled to relief." ***Northeast Fence & Iron Works, Inc. v. Murphy Quigley Co., Inc.***, 933 A.2d 664, 668 (Pa. Super. 2007), *appeal denied*, 596 Pa. 755, 947 A.2d 737 (2008).

Based upon our review of the record on appeal, we conclude that the trial court's finding that there was "simply no evidence that Wyeth knew that additional studies were necessary given the great body of scientific literature on hormone replacement therapy" was in error. The Daniels presented expert testimony and documentary evidence that Wyeth knew as early as the middle 1970s of the potential risk of breast cancer associated with the use of estrogen. In 1975, researchers proved that the use of estrogen substantially increased the risk of endometrial cancer by triggering receptors responsive to the hormone. According to Dr. Blume, these receptors are located not only in the endometrial lining of the uterus but also in other tissues of the female body, including in particular the breast. N.T. 1/10/07 (MS), at 56-57. According to Dr. Blume, given the discovery that receptors in the endometrial lining were hormone sensitive, Wyeth should have been on notice that studies were needed to assess the impact of hormone drugs on the tissues of the breast. ***Id.***

Dr. Blume further testified that in a 1976 internal memorandum, Wyeth researchers recognized a "valid concern as to whether or not the use

of exogenous estrogen leads to the increase of the incidence of breast cancer." ***Id.*** at 73. Dr. Blume described this internal memorandum as a "red flag," since in it Wyeth's researchers acknowledged "the possible role of estrogen and the combination of estrogen and progestin in the etiology of the triggering of breast cancer." ***Id.*** at 76

The record does not reflect Wyeth, despite acknowledging the existence of unanswered questions regarding possible links between the use of estrogen (independently or in combination with progestins), undertook any studies on these issues at this time. In this regard, Dr. Blume noted that in a 1977 internal memorandum, Wyeth researchers concluded that "[m]any practicing gynecologists are introducing sequential progestins into their estrogen replacement regimens in postmenopausal women." ***Id.*** at 81. The memo further acknowledged that the number of "published, well-designed studies" on the combined use of estrogen and progestin "is small or practically non-existent." ***Id.*** at 82.

In 1983, Wyeth applied to the FDA for approval to sell estrogen and progestin together in "convenience packaging" (dubbed the "Prem-Pack"). Wyeth proposed to do so based upon existing safety studies, but the FDA declined, advising Wyeth that the agency would not approve the combined use unless Wyeth first conducted human studies to identify possible safety risks. ***Id.*** at 96-97. Wyeth then applied to the FDA to initiate a study of the combined use of estrogen and progestin, representing to the FDA that "we

believe it is reasonably safe to initiate a definitive study conducted to demonstrate the efficacy and safety of the sequential usage of first Premarin and then of the Medroxyprogesterone, the progestin." ***Id.*** at 86. According to Dr. Blume, although the FDA granted Wyeth permission to conduct the study, Wyeth never did so. ***Id.*** at 91, 99-100.

In 1990, Drs. Andrew Glass and Robert Hoover published a study of their conclusions after reviewing a large data base maintained by Kaiser-Permanente, an insurance carrier on the west coast that also operates cancer treatment centers. Based upon their review of this data base, which tracked the health of women from 1960 to 1985, Drs. Glass and Hoover reported a 130% increase in hormone positive breast cancers in menopausal women in the United States over that period of time. ***Id.*** at 113-116. Dr. Blume testified that Wyeth had a contract with Kaiser for use of its data base, and thus could have performed similar studies on the rise in the number of breast cancer cases during the same period of time when the use of drug hormones (many of which were manufactured and sold by Wyeth) had steadily increased. ***Id.*** at 117-118.

Contrary to the trial court's findings, a jury could reasonably find that Wyeth knew that additional studies were required to understand the possible association between its products and breast cancer in menopausal women. In this regard, we also find that the trial court's reliance on Wyeth's compliance with the FDA's testing and labeling requirements was misplaced.

In ***Phillips v. Cricket Lighters***, 584 Pa. 179, 883 A.2d 439 (2005), our Supreme Court ruled that compliance with industry and governmental safety standards "does not, standing alone, automatically insulate a defendant from punitive damages." ***Id.*** at 191, 883 A.2d at 447. Moreover, Dr. Blume testified that the FDA's testing and labeling requirements were the "minimum standards" for a drug company, and that nothing prevents drug companies from conducting additional studies if safety concerns arise either before or after FDA approval. N.T. 1/10/07 (MS), at 48-50.

Wyeth argues that its compliance with the FDA's testing requirements, including the clinical trials (the "Prem-Pack Protocols") it conducted prior to receiving FDA approval to sell Prempro in 1994, preclude any finding that it acted with reckless indifference. Wyeth points out that federal law required the FDA to obligate drug manufacturers to conduct "adequate tests by all methods reasonably applicable" to establish a drug's safety before giving its approval. Appellee's Brief at 50 (citing 21 U.S.C. § 355(d)). We disagree. It was for the jury to decide whether Wyeth had performed adequate testing of its product before marketing it for sale. To this end, the jury was within its province to determine whether the Prem-Pack Protocols, which lasted for only one year and involved only 1,700 women, constituted adequate safety testing. The Daniels introduced testimony from Dr. Blume that the Prem-Pack Protocols were inadequate in this regard because of their purpose and scope. N.T. 1/10/07 (AS), at 52.

In sum, sufficient evidence of record exists to support a jury's finding that from the middle 1970s and forward, Wyeth knew or strongly suspected that hormone replacement therapy increased the risk of breast cancer in post-menopausal women but failed and refused to conduct adequate studies. The jury also heard testimony regarding the decrease in Wyeth's sales of Premarin in 1975 by more than 50% when the risk of endometrial cancer was revealed, and that before the results of the WHI study were released in 2002, Wyeth maintained an 80% share of the world's market for hormone therapy drugs. N.T., 1/9/07 (AS), at 20; 1/24/07 (AS), at 68. Permitting all available inferences from the evidence in favor of the verdict winner, as our standard of review requires, there was sufficient evidence to permit the jury to conclude that Wyeth's failure to perform adequate tests of the risk of breast cancer was intentional, *i.e.*, because it did not want confirmation of those risks and the resulting loss of sales and profits. Consequently, sufficient evidence of record exists to support a jury's finding that Wyeth had a subjective understanding that its sale of Prempro was placing women at an increased risk of contracting breast cancer, and its failure to test was in conscious disregard of that known risk. As such, the trial court's grant of Wyeth's JNOV motion was in error.

We turn then to the trial court's legal conclusion that federal constitutional law precluded an award of punitive damages in this case. The trial court found that "Pennsylvania may not use punitive damages to punish

Wyeth for any conduct – lawful or not – that occurred in Arkansas." Trial Court Opinion, 4/23/07, at 5. Elaborating on this finding, the trial court concluded as follows:

> All of the conduct and events relating to [Daniel's] lawsuit occurred in Arkansas, where she resided, obtained, and ingested Wyeth's drug, and developed the breast cancer she claims resulted. Wyeth's legal duty to warn was to an Arkansas doctor practicing in Arkansas, where the warning was communicated. While Pennsylvania was able to employ its courts to judge Wyeth's conduct in Arkansas for the purpose of compensating the Daniels specifically, it cannot use the courts to punish Wyeth for the purpose of vindicating Arkansas' interest in protecting its citizens. Pennsylvania courts are prohibited from attempting to vindicate the interests of Arkansas' citizens.

Id.

The trial court cites to ***BMW of North America, Inc. v. Gore***, 517 U.S. 559 (1996), as authority for its conclusions. In **BMW**, the United States Supreme Court addressed a case in which an Alabama purchaser of a new automobile brought suit in state court against the out-of-state manufacturer of the vehicle, based upon the failure to disclose to the purchaser that the car had been repainted prior to delivery to correct minor damages. ***Id.*** at 562. At trial, the manufacturer acknowledged that it had a policy since 1983 of not advising dealers or customers of fixing minor repairs if the cost of the repairs did not exceed three percent of the vehicle's suggested retail price. ***Id.*** at 562. The jury agreed with the purchaser that

this policy constituted common law fraud and awarded $4,000 in compensatory damages.

With respect to the purchaser's claim for punitive damages, he introduced evidence that pursuant to its policy of non-disclosure, the manufacturer had sold 983 cars nationwide refinished in accordance with its nondisclosure policy, including 14 in Alabama. ***Id.*** at 564. The manufacturer argued that the refinished cars it sold were of equal value to those with original factory finishes, and also pointed out that its nondisclosure policy for repairs under 3% of the car's value was expressly permitted by statute in at least 25 states. The jury disregarded these arguments and awarded the plaintiff $4 million in punitive damages ($4,000 per car multiplied by approximately 1,000 cars sold nationwide). ***Id.*** at 565. The Alabama Supreme Court refused to strike the award, but reduced it to $2 million. ***Id.*** at 567.

Focusing in part on the varying statutory provisions in other states, the U.S. Supreme Court reversed. The Court acknowledged that different states may provide differing protections for purchasers of automobiles, resulting in "a patchwork of rules representing the diverse policy judgments of lawmakers in 50 states." ***Id.*** at 570. Because no state may force its policy choices on neighboring states, the Court concluded that "a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other states." ***Id.*** at 572.

Alabama's authority to award punitive damages was limited to its own interest in "protecting its own consumers and its own economy," and thus it did not have the power "to punish BMW for conduct that was lawful where it occurred and that had no impact on Alabama or its residents." ***Id.*** at 573.

Wyeth contends that ***State Farm Mutual Automobile Insurance Co. v. Campbell***, 538 U.S. 408 (2003), also supports the trial court's decision here. In ***State Farm***, the driver of a vehicle was permanently injured and his passenger killed in an automobile accident in Utah that witnesses and investigators all attributed to an unsafe passing maneuver by another driver (Campbell, insured by State Farm). ***Id.*** at 412-13. State Farm decided to contest liability at trial and refused offers to settle the case for the policy limit of $50,000. ***Id.*** at 413. A jury determined that Campbell was 100% negligent and awarded over $185,000 in compensatory damages. ***Id.***

Campbell thereafter filed suit in Utah state court against State Farm, alleging bad faith, fraud, and intentional infliction of emotional distress. ***Id.*** at 414. At trial, Campbell introduced evidence that State Farm's conduct in taking the case to trial was part of a national scheme to meet corporate fiscal goals by capping payouts on claims. ***Id.*** at 415. The jury awarded Campbell $2.6 million in compensatory damages and $145 million in punitive damages. ***Id.*** at 415. Although the trial court reduced the damages to $1 million and $25 million, respectively, the Utah Supreme Court reinstated the $145 million punitive damages award. ***Id.*** at 415.

The U.S. Supreme Court reversed, in part based upon the Utah Supreme Court's express acknowledgement that the punitive damages award was intended to punish State Farm for unlawful conduct outside the state of Utah, *i.e.*, for its *national* scheme to meet corporate goals:

> A State cannot punish a defendant for conduct that may have been lawful where it occurred. … Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction. Any proper adjudication of conduct that occurred outside Utah to other persons would require their inclusion, and, to those parties, the Utah courts, in the usual case, would need to apply the laws of their relevant jurisdiction.

Id. at 421-22.

In our view, neither ***BMW*** nor ***State Farm*** imposes any constitutional limitation on an award of punitive damages against Wyeth, since in both cases the limitations prescribed by the Supreme Court were on the corporate defendant's *out-of-state* conduct. In ***BMW***, the Court reversed the grant of punitive damages because part of the conduct punished occurred in states where it was legal, ***BMW***, 517 U.S. at 574, and in ***State Farm*** the Court reversed because the reward was based upon "unlawful acts committed outside of [Utah's] jurisdiction." ***State Farm***, 538 U.S. at 421-22. In neither case did the Court suggest any constitutional limitation on awards of punitive damages for conduct occurring within the state imposing the penalties.

In the present case, the trial court erred by confusing conduct relevant to the award of *compensatory damages* with the conduct relevant to assessing *punitive damages*. While it is true that Daniel resided in Arkansas and obtained and ingested Wyeth's drug in Arkansas after her Arkansas doctor received and communicated the contents of Wyeth's warning labels there, this conduct is relevant principally, if not exclusively, to the Daniels' claims for compensatory damages. In contrast, all of Wyeth's conduct relevant to the jury's assessment of the award of punitive damages occurred in Pennsylvania. Wyeth is a Pennsylvania corporation with its principal place of business in King of Prussia. N.T., 1/9/07 (MS), at 59.[16] Its corporate decisions regarding the failure or refusal to conduct adequate testing to determine whether its products increased the risk of breast cancer in post-menopausal women occurred primarily (if not exclusively) in Pennsylvania, where corporate leadership is located. Wyeth's subjective appreciation of the risk of harm to which it was subjecting Daniel, and its failure to act, in

[16] Wyeth does not contest these facts. In its opening statement at trial, counsel for Wyeth represented to the jury that it is "a Philadelphia company. It started over on Walnut Street actually over a hundred years ago. Now [it is] out in the King of Prussia area. Basically, [it is] headquartered out there." ***Id.***; ***see, e.g.***, ***Coleman v. Wyeth Pharmaceuticals, Inc.***, 2010 WL 3385964 *19 (Pa. Super., August 30, 2010) ("Statements of fact by one party in pleadings, stipulations, testimony, and the like, made for that party's benefit, are termed judicial admissions and are binding on the party.") (quoting ***Nasim v. Shamrock Welding Supply Co.***, 563 A.2d 1266, 1267 (1989) ("[a] judicial admission is an express waiver made in court or preparatory to trial by a party or his attorney, conceding for the purposes of trial, the truth of the admission"), *appeal denied*, 525 Pa. 619, 577 A.2d 890 (1990)).

conscious disregard of that risk, occurred in Pennsylvania. Accordingly, punitive damages are properly assessed here, in accordance with Pennsylvania law.[17]

For these reasons, the trial court's order dated August 24, 2007 granting Wyeth's post-trial motion for a new trial is hereby reversed, and the jury's verdict on compensatory damages is reinstated. Likewise, the trial court's order dated January 30, 2007 granting Wyeth's post-trial motion for JNOV on punitive damages is also reversed, and the jury's verdict awarding punitive damages is reinstated.[18] Wyeth's cross-appeal is denied.

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[17] Because the conduct forming the basis for the assessment of punitive damages occurred in Pennsylvania, Pennsylvania choice of law rules require the application of Pennsylvania punitive damages law. Here we find persuasive ***Kelly v. Ford Motor Company***, 933 F. Supp. 465, 469-71 (E.D. Pa. 1996), in which the federal district court concluded that in a choice of law analysis on the availability of punitive damages, "the most critical contacts include the place where the alleged punitive conduct occurred and, if dealing with a corporate defendant, the state of incorporation and its principal place of business. … In the instant case, the evidence is uncontradicted that all of the relevant conduct, including the development activity, design, testing, and decision-making relating to the allegedly-defective Bronco II, took place at Ford's headquarters in Dearborn, Michigan.").

In this regard, we note that both the Daniels and Wyeth agree that Pennsylvania law applies with regard to the availability of punitive damages in this case, as both strongly urged the application of the legal standards set forth by our Supreme Court in ***Hutchison ex rel. Hutchison v. Luddy***, 582 Pa. 114, 870 A.2d 766 (2005). Brief of Appellants' at 46; Brief of Appellee at 47-48.

[18] We do not agree with the learned author of the Concurring Opinion that Wyeth retains the right to challenge the amount of the punitive damages award. As explained in detail in footnote 6 ***supra***, Wyeth raised the issue of the amount of punitive damages awarded by the jury in its Rule 1925(b)

Fitzgerald, J. files a Concurring Opinion.

statement of matters complained of on appeal, but subsequently waived this issue by failing to include any mention of it in its appellate brief.

2011 PA Super 23

MARY DANIEL and THOMAS DANIEL, SR.,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellants	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH LABORATORIES, INC., WYETH PHARMACEUTICALS, DIV. OF WYETH, DIV. OF AMERICAN HOME PRODUCTS CORP., WYETH, INC. A/K/A AMERICAN HOME PRODUCTS CORP.,	:	
	:	
Appellees	:	No. 2626 EDA 2007

Appeal from the Order entered August 24, 2007,
Court of Common Pleas, Philadelphia County,
Civil Division at No. June Term, 2004, No. 002368

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MARY DANIEL and THOMAS DANIEL, SR.,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellees	:	
	:	
v.	:	
	:	
WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH LABORATORIES, INC., and WYETH PHARMACEUTICALS, DIVISION OF WYETH,	:	
	:	
Appellants	:	No. 2690 EDA 2007

*Former Justice specially assigned to the Superior Court.

Appeal from the Order entered August 24, 2007,
Court of Common Pleas, Philadelphia County,
Civil Division at No. June Term, 2004, No. 002368
BEFORE: DONOHUE, ALLEN and FITZGERALD*, JJ.

CONCURRING OPINION BY FITZGERALD, J.:

After a review of the certified record[1] and because of the unique facts, the trial and appellate procedural history, and the issues preserved, raised, and waived on appeal, I concur only in the result reached by the learned majority.

I write separately to note my concern that the majority's seeming emphasis on *where* the conduct warranting punitive damages originated shifts the focus away from *whether* the harmful conduct was directed to the injured plaintiff or to non-parties, such as all "post-menopausal women," or non-Pennsylvania consumers. ***See generally Philip Morris USA v.***

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* Former Justice specially assigned to the Superior Court.

[1] The certified record—remarkably sparse for a case of this type—did not include, among many other seemingly key documents, the trial exhibits and assorted post-trial motions. "In this regard, our law is the same in both the civil and criminal context because, under the Pennsylvania Rules of Appellate Procedure, any document which is not part of the officially certified record is deemed non-existent—a deficiency which cannot be remedied merely by including copies of the missing documents in a brief or in the reproduced record. . . . Simply put, if a document is not in the certified record, the Superior Court may not consider it." ***Commonwealth v. Preston***, 904 A.2d 1, 6-7 (Pa. Super. 2006) (*en banc*) (citations omitted). It is, of course, the appellant's responsibility to ensure the record is complete prior to its transmission to this Court. ***See generally Commonwealth v. Williams***, 552 Pa. 451, 458-60, 715 A.2d 1101, 1104-05 (1998); ***Kessler v. Broder***, 851 A.2d 944, 950 (Pa. Super. 2004). The missing documents impeded effective appellate review.

Williams, 549 U.S. 346, 353-55, 127 S. Ct. 1057, 1063-64, 166 L. Ed. 2d 940, 948-49 (2007);[2] ***State Farm Mut. Auto. Ins. Co. v. Campbell***, 538 U.S. 408, 422, 123 S. Ct. 1513, 1522, 155 L. Ed. 2d 585, 604 (2003) (holding, "Lawful out-of-state conduct may be probative when it demonstrates the deliberateness and culpability of the defendant's action in the State where it is tortious, but that conduct must have a nexus to the specific harm suffered by the plaintiff.").[3] Regardless, I am unaware of any suggestion the conduct at issue was dissimilar to the conduct that harmed Appellants and did not implicate Pennsylvania's interests "in protecting its

[2] I acknowledge this decision was filed after the jury's verdict. The United States Supreme Court held, "In our view, the Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent, *i.e.*, injury that it inflicts upon those who are, essentially, strangers to the litigation." ***Philip Morris USA***, 549 U.S. at 353, 127 S. Ct. at 1063, 155 L. Ed. 2d at 948.

[3] In determining "Wyeth is a Pennsylvania corporation with its principal place of business in King of Prussia," the majority cites counsel's opening statement. Initially, I note that we, as an appellate court, should avoid reaching factual conclusions. ***See Commonwealth v. Jackson***, 464 Pa. 292, 298, 346 A.2d 746, 748 (1975). I am also hesitant to elevate counsel's opening claims into a finding of fact, particularly when the fact-finder had not yet heard any evidence. N.T., 1/9/07, at 6 (court informing jury that "nothing the lawyers say" is evidence); ***see*** Pa. Suggested Standard Civil Jury Instructions § 1.36 (3d ed. 2005) (instructing jurors that opening statements by counsel are not evidence). Although I do not join the majority's rationale, I concur in the result because Appellees had, but declined, the opportunity to challenge Appellants' contention that the nerve center—where three decades of corporate decisions warranting punitive damages allegedly occurred—was at, for example, Wyeth-Ayerst Pharmaceuticals, Inc., in Collegeville, Pennsylvania, as opposed to, for example, Wyeth, Inc., in Madison, New Jersey.

own consumers and its own economy." ***BMW of N. Am., Inc. v. Gore***, 517 U.S. 559, 572, 116 S. Ct. 1589, 1597, 134 L. Ed. 2d 809, 825 (1996); ***see Campbell***, 538 U.S. at 422, 123 S. Ct. at 1523, 155 L. Ed. 2d at 604. I also express my belief, however, that because this Court is reinstating the award of punitive damages, Appellees retain the ability to challenge the amount of punitive damages.